AMENDMENTS TO THE CLAIMS

This Listing of Claims will replace all prior versions and listings of the claims in this application:

Listing of Claims:

1. (currently amended) A solid oral dosage form comprising a hydrophilic or macromolecular drug and, as an enhancer for delivery to an intestine, a salt of a medium chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms, wherein said ~~composition~~ dosage form and each of said constituents and any other constituent comprising the ~~composition is~~ dosage form are a solid at room temperature.

2. (canceled)

3. (original) The solid oral dosage form of claim 1, wherein the carbon chain length is from 8 to 14 carbon atoms.

4. (previously presented) The solid oral dosage form of claim 1 wherein the enhancer is a sodium salt of a medium chain fatty acid.

5. (original) The solid oral dosage form according to claim 4, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate and sodium laurate.

6. (original) The solid oral dosage form according to claim 1, wherein the drug is a polysaccharide, an oligosaccharide, a protein or a peptide.

7. (original) The solid oral dosage form according to claim 6, wherein the polysaccharide is low molecular weight heparin.

8. (withdrawn) The solid oral dosage form according to claim 6, wherein the peptide is luteinising hormone-releasing hormone analog.

9. (withdrawn) The solid oral dosage form according to claim 1, wherein the drug is selected from the group consisting of TRH, unfractionated heparin, insulin, luteinising hormone-releasing hormone (LHRH), leuprolide, goserelin, genotropin, nafarelin, buserelin, alendronate, cyclosporine, calcitonin, vasopressin, desmopressin and salts thereof.

10. (original) The solid oral dosage form of claim 1, wherein the drug and the enhancer are present in a ratio of from 1:100,000 to 10:1 (drug : enhancer).

11. (original) The solid oral dosage form of claim 1, wherein the dosage form is a tablet, a capsule or a multiparticulate dosage form.

12. (currently amended) The solid oral dosage form of claim 11, wherein the dosage form is a ~~controlled~~ delayed release dosage form.

13. (previously presented) The solid oral dosage form of claim 11, wherein the dosage form further comprises a rate-controlling polymer material.

14. (previously presented) The solid oral dosage form of claim 13, wherein the rate-controlling polymer material is HPMC.

15. (previously presented) The solid oral dosage form of claim 13, wherein the rate-controlling polymer material is a polymer derived from acrylic or methacrylic acid and their respective esters or copolymers derived from acrylic or methacrylic acid and their respective esters.

16. (previously presented) The solid oral dosage form of claim 13, wherein the drug and enhancer and at least one auxiliary excipient are compressed into tablet form prior to coating with a rate controlling polymer material.

17. (original) The solid oral dosage form of claim 12, wherein the drug and enhancer and at least one auxiliary excipient are compressed into tablet form prior to coating with a delayed release polymer.

18-20. (canceled)

21. (previously presented) The solid oral dosage form of claim 13, wherein the drug, the enhancer and at least one auxiliary excipient are compressed into the form of a multilayer tablet prior to coating with the rate controlling-polymer material.

22. (original) The solid oral dosage form of claim 12, wherein the drug, the enhancer and at least one auxiliary excipient are compressed into the form of a multilayer tablet prior to coating with a delayed release polymer.

23. (original) The solid oral dosage form of claim 13, wherein the drug and enhancer are dispersed in the rate-controlling polymer material and compressed into the form of a multilayer tablet.

24. (previously presented) The solid oral dosage form of claim 23, wherein the multilayer tablet is coated with a rate-controlling polymer material.

25. (original) The solid oral dosage form of claim 23, wherein the multilayer tablet is coated with a delayed release polymer.

26. (original) The solid oral dosage form according to claim 13, wherein the drug, the enhancer, at least one auxiliary excipient, and the rate-controlling polymer material are combined into a multiparticulate form.

27. (previously presented) The solid oral dosage form according to claim 26, wherein the multiparticulate form comprises discrete particles, pellets, minitablets, or combinations thereof.

28. (previously presented) The solid oral dosage form according to claim 27 comprising a blend of two or more populations of particles, pellets or mini-tablets having different in vitro or in vivo release characteristics.

29. (previously presented) The solid oral dosage form according to claim 26, wherein the multiparticulate is encapsulated in hard or soft gelatin capsules.

30. (previously presented) The solid oral dosage form according to claim 29, wherein the capsule is coated with a rate-controlling polymer material.

31. (original) The solid oral dosage form according to claim 29, wherein the capsule is coated with a delayed release polymer.

32. (previously presented) The solid oral dosage form according to claim 26, wherein the multiparticulate is incorporated into a sachet.

33. (previously presented) The solid oral dosage form according to claim 27, wherein the discrete particles or pellets are compressed into tablet form.

34. (previously presented) The solid oral dosage form according to claim 33, wherein the tablet form is coated with a rate controlling polymer material.

35. (previously presented) The solid oral dosage form according to claim 33, wherein the tablet form is coated with a delayed release polymer.

36. (previously presented) The solid oral dosage form according to claim 27, wherein the discrete particles or pellets are compressed into a multilayer tablet.

37. (previously presented) The solid oral dosage form according to claim 36 wherein the multilayer tablet is coated with a rate controlling polymer material.

38. (previously presented) The solid oral dosage form according to claim 36 wherein the multilayer tablet is coated with a delayed release polymer.

39. (currently amended) A method of treatment of a medical condition comprising administering orally to a patient suffering from said medical condition a therapeutically effective amount of ~~a dose of~~ a composition which is in solid form and which comprises a hydrophilic or macromolecular drug effective in treating the medical condition and, as an enhancer for delivery to an intestine, a salt of a medium chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms, wherein said composition and each of said constituents and any other constituent comprising the composition ~~is~~ are a solid at room temperature.

40. (canceled)

41. (currently amended) A process for the manufacture of a composition in solid oral dosage form comprising the steps of:

a) providing a blend of a hydrophilic or macromolecular drug and, as an enhancer for delivery to an intestine:

(i) a salt of a medium chain fatty acid ~~or salt thereof~~ having a carbon chain length of from 6 to 20 carbon atoms;

(ii) a medium chain fatty acid halide derivative, a medium chain fatty acid anhydride derivative, or a medium chain fatty acid glyceride derivative, each of said derivatives having a carbon chain length of from 6 to 20 carbon atoms; or

(iii) the fatty acid salt of clause (i) having, at the end opposite the fatty acid salt, an acid halide, an acid anhydride, or glyceride moiety;

(iv) an acid halide derivative of clause (ii) above having, at the end opposite of the halide portion, an acid halide, acid anhydride, or glyceride moiety;

(v) an anhydride derivative of clause (ii) above having, at the end opposite of the anhydride, an acid anhydride, acid halide, or glyceride moiety; or

(vi) a glyceride derivative of clause (ii) above having, at the end opposite of the glyceride portion, a glyceride, an acid halide, or acid anhydride moiety;

which blend also comprises, optionally, another constituent(s); wherein said blend and each of said drug, enhancer, and optional constituent(s) is a solid at room temperature; and

b) forming said solid oral dosage form of the composition from the blend by:

i) direct compression of the blend; or

ii) granulating the blend to form a granulate for incorporation into said solid oral dosage form.

42. (previously presented) The process according to claim 41 wherein the drug and the enhancer are blended in a ratio of from 1:100,000 to 10:1 (drug: enhancer).

43-46. (canceled)

47. (currently amended) A pharmaceutical composition ~~in solid oral dosage form~~ comprising a hydrophilic or macromolecular drug and, as an enhancer for delivery to an intestine:

(i) a salt of a medium chain fatty acid ~~or salt thereof~~ having a carbon chain length of from 6 to 20 carbon atoms;

(ii) a medium chain fatty acid halide derivative, a medium chain fatty acid anhydride derivative, or a medium chain fatty acid glyceride derivative, each of said derivatives having a carbon chain length of from 6 to 20 carbon atoms;
(iii) the fatty acid salt of clause (i) having, at the end opposite the fatty acid salt, an acid halide, acid anhydride, or glyceride moiety;
(iv) an acid halide derivative of clause (ii) above having, at the end opposite of the halide portion, an acid halide, acid anhydride, or glyceride moiety;
(v) an anhydride derivative of clause (ii) above having, at the end opposite of the anhydride, an acid anhydride, acid halide, or glyceride moiety; or
(vi) a glyceride derivative of clause (ii) above having, at the end opposite of the glyceride portion, a glyceride, acid halide, or acid anhydride moiety;
which blend also comprises, optionally, another constituent(s), and wherein said composition and each of said constituents and any other constituent comprising the composition ~~is~~ are a solid at room temperature.

48. (canceled)

49. (original) The solid oral dosage form according to claim 11, wherein the dosage form is a capsule.

50. (previously presented) The solid oral dosage form according to claim 49, wherein the capsule is coated with a rate controlling polymer material.

51. (previously presented) The solid oral dosage form according to claim 49 wherein the capsule is coated with a delayed release polymer.

52. (canceled)

53. (currently amended) A solid oral dosage form comprising a hydrophilic or macromolecular drug and, as the only enhancer present in the dosage form, one or

more members selected from the group consisting of a salt of a fatty acid which has a carbon chain length of from 6 to 20 carbon atoms.

54. (previously presented) The solid oral dosage form of claim 53, wherein the enhancer is one or more members selected from the group consisting of a salt of a fatty acid having a carbon chain length of from 8 to 14 carbon atoms.

55. (previously presented) The solid oral dosage form of claim 53 wherein said fatty acid salt is a sodium salt.

56. (previously presented) The solid oral dosage form of claim 55, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate and sodium laurate.

57. (previously presented) The solid oral dosage form of claim 53, wherein the drug is a polysaccharide, an oligosaccharide, a protein or a peptide.

58. (previously presented) The solid oral dosage form of claim 57, wherein said polysaccharide is low molecular weight heparin.

59. (withdrawn) The solid oral dosage form of claim 57, wherein the peptide is luteinising hormone-releasing hormone analog.

60. (withdrawn) The solid oral dosage form of claim 53, wherein the drug is selected from the group consisting of TRH, unfractionated heparin, insulin, luteinising hormone-releasing hormone (LHRH), leuprolide, goserelin, genotropin, nafarelin, buserelin, alendronate, cyclosporine, calcitonin, vasopressin, desmopressin and salts thereof.

61. (previously presented) The solid oral dosage form of claim 53, wherein the drug and the enhancer are present in a weight ratio of from 1:100000 to 10:1 (drug : enhancer).

62. (previously presented) The solid oral dosage form of claim 53 selected from the group consisting of a tablet, a capsule, and a multiparticulate.

63. (currently amended) A method of treatment of a medical condition comprising administering orally to a patient suffering from said medical condition a solid dosage form containing a therapeutically effective amount of a hydrophilic or macromolecular drug effective in treating the medical condition and, as the only enhancer present in the dosage form, one or more members selected from the group consisting of a salt of a fatty acid which has a carbon chain length of from 6 to 20 carbon atoms.

64. (currently amended) A process for the manufacture of a solid oral dosage form comprising the steps of:

i) providing a blend of a hydrophilic or macromolecular drug and, as the only enhancer present in the dosage form, one or more members selected from the group consisting of: a) an acid salt, acid halide, acid anhydride, or glyceride derivative of a fatty acid having a carbon chain length of from 6 to 20 carbon atoms; and b) a derivative of clause a) which is difunctional in that it has, on the end of the carbon chain opposite the acid salt group, an acid halide, an acid anhydride, or a glyceride moiety; and

ii) forming said solid oral dosage form of the composition from the blend by:
   a) direct compression of the blend; or
   b) granulating the blend to form a granular material.

65. (currently amended) A composition ~~in solid oral dosage form~~ comprising a hydrophilic or macromolecular drug and, as the only enhancer present in the dosage form, one or more members selected from the group consisting of:

(a) an acid salt, acid halide, acid anhydride, or glyceride of a fatty acid having a carbon chain length of from 6 to 20 carbon atoms; and

(b) a derivative of clause (a) which is a difunctional in that it has on the end of the carbon chain opposite the acid salt group an acid halide, an acid anhydride, or a glyceride moiety.

66. (previously presented) The composition of claim 65 wherein the drug, the enhancer, and any other constituent present in the composition is a solid at room temperature.

67. (withdrawn) The solid oral dosage form of claim 1, wherein the drug is a therapeutically effective amount of a bisphosphonate.

68. (withdrawn) The solid oral dosage form according to claim 67 and including about 0.5 μg to about 1,000 mg of the bisphosphonate.

69. (withdrawn) The solid oral dosage form according to claim 68 in which the bisphosphonate and the enhancer are present in a ratio of from 1:100,000 to 10:1 (bisphosphonate : enhancer).

70. (withdrawn) The solid oral dosage form according to claim 69, wherein the ratio is from 1:1,000 to 10:1.

71. (withdrawn) The solid oral dosage form according to claim 67, wherein the bisphosphonate is alendronate.

72. (withdrawn) The solid oral dosage form according to claim 68, wherein the bisphosphonate is alendronate.

73. (withdrawn) The solid oral dosage form according to claim 69, wherein the bisphosphonate is alendronate.

74. (withdrawn) The solid oral dosage form according to claim 70, wherein the bisphosphonate is alendronate.

75. (withdrawn) The solid oral dosage form according to claim 67, wherein the fatty acid has a carbon chain length of from 8 to 14 carbon atoms.

76. (withdrawn) The solid oral dosage form according to claim 68, wherein the fatty acid has a carbon chain length of from 8 to 14 carbon atoms.

77. (withdrawn) The solid oral dosage form according to claim 69, wherein the fatty acid has a carbon chain length of from 8 to 14 carbon atoms.

78. (withdrawn) The solid oral dosage form according to claim 70, wherein the fatty acid has a carbon chain length of from 8 to 14 carbon atoms.

79. (withdrawn) The solid oral dosage form according to claim 71, wherein the fatty acid has a carbon chain length of from 8 to 14 carbon atoms.

80. (withdrawn) The solid oral dosage form according to claim 72, wherein the fatty acid has a carbon chain length of from 8 to 14 carbon atoms.

81. (withdrawn) The solid oral dosage form according to claim 73, wherein the fatty acid has a carbon chain length of from 8 to 14 carbon atoms.

82. (withdrawn) The solid oral dosage form according to claim 74, wherein the fatty acid has a carbon chain length of from 8 to 14 carbon atoms.

83. (withdrawn) The solid oral dosage form according to claim 71, wherein the bisphosphonate is etidronate.

84. (withdrawn) The solid oral dosage form of claim 67 in delayed release form and comprising a tablet which has thereon an enteric coating.

85. (withdrawn) The solid oral dosage form of claim 84, wherein the bisphosphonate and the enhancer are present in a ratio of from 1:1,000 to 10:1 (drug:enhancer).

86. (withdrawn) The solid oral dosage form of claim 85 wherein the enhancer is sodium caprate.

87. (new) The solid oral dosage form of claim 53 wherein the drug, the enhancer, and any other constituent present in the composition are a solid at room temperature.

88. (new) A solid composition capable of being formed into a solid oral dosage form for delivery to an intestine and which comprises a hydrophilic or macromolecular drug and, as an enhancer, a salt of a medium chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms, wherein each of said constituents and any other constituent comprising the composition are a solid at room temperature.

89. (new) The composition of claim 88, wherein the carbon chain length is from 8 to 14 carbon atoms.

90. (new) The composition of claim 88, wherein the enhancer is a sodium salt of a medium chain fatty acid.

91. (new) The composition of claim 90, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate and sodium laurate.

92. (new) The composition of claim 88, wherein the drug is a polysaccharide, an oligosaccharide, a protein or a peptide.

93. (new) The composition of claim 92, wherein the polysaccharide is low molecular weight heparin.

94. (new) The composition of claim 88, wherein the drug and the enhancer are present in a ratio of from 1:100,000 to 10:1 (drug : enhancer).

95. (new) The composition of claim 88 wherein the salt of a medium chain fatty acid is the only enhancer present in the composition.

96. (new) A process for the preparation of a solid composition which is capable of being formed into a solid oral dosage form for delivery to an intestine comprising the step of:

a) providing a blend of a hydrophilic or macromolecular drug and, as an enhancer:

(i) a salt of a medium chain fatty acid having a carbon chain length of from 6 to 20 carbon atoms;

(ii) a medium chain fatty acid halide derivative, a medium chain fatty acid anhydride derivative, or a medium chain fatty acid glyceride derivative, each of said derivatives having a carbon chain length of from 6 to 20 carbon atoms; or

(iii) the fatty acid salt of clause (i) having, at the end opposite the fatty acid salt, an acid halide, an acid anhydride, or glyceride moiety;

(iv) an acid halide derivative of clause (ii) above having, at the end opposite of the halide portion, an acid halide, acid anhydride, or glyceride moiety;

(v) an anhydride derivative of clause (ii) above having, at the end opposite of the anhydride, an acid anhydride, acid halide, or glyceride moiety; or

(vi) a glyceride derivative of clause (ii) above having, at the end opposite of the glyceride portion, a glyceride, an acid halide, or acid anhydride moiety;

which blend also comprises, optionally, another constituent(s); wherein said blend and each of said drug, enhancer, and optional constituent(s) is a solid at room temperature.

97. (new) The process according to claim 96 wherein the drug and the enhancer are blended in a ratio of from 1:100,000 to 10:1 (drug: enhancer).

98. (new) A solid composition which is capable of being formed into a solid oral dosage form for delivery to an intestine comprising a hydrophilic or macromolecular drug and, as the only enhancer present in the composition, one or more members selected from the group consisting of a salt of a fatty acid which has a carbon chain length of from 6 to 20 carbon atoms.

99. (new) The composition of claim 98, wherein the enhancer is one or more members selected from the group consisting of a salt of a fatty acid having a carbon chain length of from 8 to 14 carbon atoms.

100. (new) The composition of claim 98, wherein said fatty acid salt is a sodium salt.

101. (new) The composition of claim 100, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate and sodium laurate.

102. (new) The composition of claim 98, wherein the drug is a polysaccharide, an oligosaccharide, a protein or a peptide.

103. (new) The composition of claim 102, wherein said polysaccharide is low molecular weight heparin.

104. (new) The composition of claim 98, wherein the drug and the enhancer are present in a weight ratio of from 1:100000 to 10:1 (drug : enhancer).

105. (new) A process for the preparation of a solid composition which is capable of being formed into a solid oral dosage form for delivery to an intestine comprising the step of:

i) providing a blend of a hydrophilic or macromolecular drug and, as the only enhancer present in the dosage form, one or more members selected from the group consisting of: a) an acid salt, acid halide, acid anhydride, or glyceride derivative of a fatty acid having a carbon chain length of from 6 to 20 carbon atoms; and b) a derivative of clause a) which is difunctional in that it has, on the end of the carbon chain opposite the acid salt group, an acid halide, an acid anhydride, or a glyceride moiety.

106. (new) A solid composition which is capable of being formed into a solid oral dosage form for delivery to an intestine and which comprises a low molecular weight heparin and, as an enhancer, sodium caprate, wherein said composition and each of said constituents and any other constituent comprising the composition are a solid at room temperature.

107. (new) The composition of claim 106 in the form of a solid oral dosage form.

108. (new) A solid composition which is capable of being formed into a solid oral dosage form for delivery to an intestine and which comprises low molecular weight heparin and, as the only enhancer present in the composition, sodium caprate.

109. (new) The composition of claim 108 in the form of a solid oral dosage form.